REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance.

Claims 1-10 and 13-22 are pending in the application. Claims 1-10 and 13-22 remain unchanged. Claims 25, 30 and 31 have been canceled without prejudice or disclaimer and may be the subject of a further application.

Claims 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, for allegedly not satisfying the enablement requirement.

The cancellation of Claims 30 and 31 obviate these rejections. Applicants respectfully request that the rejections be withdrawn.

Claims 1-10, 13-22, 25, 30 and 31 are rejected under 35 U.S.C. 103(a) as allegedly being obvious over U.S. Patent No. 5,502,077 in the name of BREIVIK et al. and U.S. Patent No. 4,935243 in the name of BORKAN et al. This rejection is traversed.

BREIVIK exemplifies a soft gelatin capsule containing a formulation comprising *ethyl esters* of EPA and DHA. The reference speculates that the EPA and the DHA formulation could be in the form of the free acid. However, such an embodiment is not exemplified. There is no disclosure in this reference of the use of any particular type of gelatin, let alone a suggestion to use either Type A gelatin or Type B gelatin to form soft gelatin capsules containing omega-3 polyunsaturated fatty acids *in free acid form*. The skilled person considering BREIVIK could not have appreciated that stability could be

improved by using Type A gelatin in place of Type B gelatin to form the capsules. Plainly, BREIVIK fails to disclose or suggest the soft gelatin capsule containing an omega-3 polyunsaturated fatty acid in free acid form and Type A gelatin as recited in the claims.

BORKAN fails to remedy the deficiencies of BREIVIK for reference purposes. BORKAN is concerned solely with the problem of providing a soft gelatin capsule that is readily chewable and edible, which is clearly not the problem addressed in the present application.

The solution taught in BORKAN is to incorporate hydrogenated starch hydrosylate into the gelatin composition for forming the capsule. Whilst the resultant capsules are readily chewable thereby solving the problem to which BORKAN is addressed, the reference provides no indication that the rate of disintegration of soft Type B gelatin capsules containing a free omea-3 polyunsaturated fatty acid formulation may decrease over time more quickly than capsules made from Type A gelatin.

At column 3, lines 39-44, BROKAN states that "The gelatin may be of Type A, Type B, or a mixture thereof. Bloom numbers, the indicator of gelatin strength, may range from about 60-300." Thus, BORKAN teaches that any type of gelatin may be used so long as the bloom strength is in a certain range. In this regard, BORKAN actually evidences the unexpected nature and nonobviousness of the claimed invention.

Applicants respectfully submit that one skilled in the art would lack the motivation to combine and modify BREIVIK and BORKAN to obtain the claimed invention.

In the specification of the present application (see page 5, lines1-6), it is clearly

stated that the skilled person would not have expected Type A gelatin to behave differently from Type B gelatin, especially since the chemical structure of the two types of gelatin is essentially the same.

The primary difference between the two types of gelatin arises from the manufacturing processes. In this connection, Type A gelatins are usually derived from acid pre-treated pigskin and have an isoelectric point between pH 7 and pH 9, with the higher gel strength gelatins having a higher isoelectric point and the low gel strength gelatins having an isoelectric point closer to pH 6. In contrast, Type B gelatins are typically derived from alkaline treated limed hide or limed ossein and have typically an isoelectric point of about pH 5. Type A gelatin is generally adjusted to an acidic pH below the isoelectric point to obtain cationic properties. On the other hand, the pH of Type B gelatin is generally adjusted to obtain anionic properties.

As acknowledged in the present application, the different processes for manufacturing gelatin were known at the priority date. The differences in isoelectric point and net charge were also known, for example, from US 6,465,626. However, the inventors of the present application have been the first to consider that Type A gelatin might increase the shelf life of soft gelatin capsules containing free omega-3 polyunsaturated fatty acid formulation when compared to equivalent capsules made from Type B gelatin. In fact, based upon the perceived interchangeability of the different types of gelatin in the prior art, the skilled person clearly would not have expected the shelf life of the soft Type A gelatin capsules to be any different from the the soft Type B gelatin capsules.

The inventors have discovered for the first time that Type B gelatin is surprisingly susceptible (and significantly more susceptible than Type A gelatin) to interaction with omega-3 polyunsaturated fatty acids, forming reactive oxidative decomposition products such as alcohols, aldehydes and ketones. It is currently believed that the net charge of the gelatin is likely to have a dominant effect. The chemistry of the free omea-3 polyunsaturated fatty acids is of course governed not only by the Lewis acidity, but also by amphiphilic properties and a *cis*-doubled bond system, thereby allowing not only covalent but also free radical reactions.

It is clear that the interaction of Type B gelatin with free omega-3 polyunsaturated fatty acids results in an unexpected increase in the rate of "aging" of the capsules, which includes visible effects such as formation of a skin or "pellicle" at the interface between the free polyunsaturated fatty acids and the gelatin (See page 2, line 32 to page line 24).

The inventors have also discovered that the rate of disintegration of soft Type B gelatin capsules containing a free omega-3 polyunsaturated fatty acid formulation decreases over time. They have also discovered that the rate of disintegration of equivalent capsules made from Type A gelatin does not decrease to anywhere near the same extent over the same period of time (See page 3, lines 26-34). Without actually making soft Type A or Type B gelatin capsules containing a free polyunsaturated fatty acid formulation and measuring the disintegration time after storage of the capsules over time, it would <u>not</u> have been possible for one skilled in the art to deduce (i.e. from hardcopy references only) that the shelf life of the capsules may be improved by using

Type A gelatin in place of Type B gelatin to form the capsules (See page 3, last full paragraph).

On this basis, the skilled person simply could not have appreciated from the prior art that there was a stability issue with the Type B gelatin capsules which could not be solved by using Type A gelatin in place of the Type B gelatin.

The Examiner's attention is respectfully directed to Table 1 on page 10 in the present specification. Table 1 compares the stability of gelatin capsules prepared with Type A gelatin relative to Type B gelatin. The results indicate that, for the Type B gelatin capsules stored at a given temperature, there is a general increase in disintegration times as the storage time or temperature increases. These results are consistent with the omega-3 polyunsaturated fatty acid interacting chemically with the Type B gelatin resulting in a hardening of the capsule wall. These results stand in contrast to capsules prepared with Type A gelatin, which exhibit improved disintegration times and shelf life when subjected to the same conditions as capsules prepared with Type B gelatin.

The Examiner is respectfully reminded that the Patent Office must consider objective indicia of nonobviousness whenever present. Specifically, the Patent Office is bound to consider evidence of unexpected results, commercial success, long-felt but unresolved needs, failure of others, skepticism of experts. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 f. 2d 1530, 1538 (Fed Cir. 1983). Federal Circuit precedent mandates consideration of evidence already present in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness

of the claims. *In re Margolis*, 785 F. 2d 1029 (Fed Cir. 1986). (Vacating Board decision which refused to consider data in the specification which compared an embodiment of the invention with the prior art product and noting that such evidence spoke to unexpected results and non-obviousness).

Thus, contrary to what one skilled in the art would have expected, the results in the specification confirm that the use of Type A gelatin in a soft gelatin capsule comprising omega-3 polyunsaturated fatty acids in free acid form unexpectedly provides a soft gel capsule having improved shelf stability and disintegration times. The selection of Type A gelatin certainly does not reflect the optimization of a routine condition such as temperature or pH as advocated by the Official Action on the top of page 8.

In view of the above, Applicants respectfully submit that the proposed combination of BREIVIK and BORKAN fail to render obvious the claimed invention. Applicants respectfully request that the obviousness rejection be withdrawn.

Claims 1-10 and 13-22 and 30-31 stand rejected for obviousness-type double patenting over claims 1-17 of U.S. Patent No. 5,792,795 and the claims of U.S. Patent No. 5,948,818. This rejection is traversed.

A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one claim is not patentably distinct from the reference claim(s) because the claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The claims of both U.S. Patent 5,792,795 and U.S. Patent No. 5,948,818 recite an oral dosage in the form of a soft gelatin capsule. However, there is suggestion in any of the claims of a particular type of gelatin, let alone Type A gelatin.

A double patenting rejection of the obviousness-type, if not based on an anticipation rationale, is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, the analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

As noted above, the claimed invention is based on the unexpected observation that soft gelatin capsules containing polyunsaturated fatty acids in free acid form are significantly more stable when prepared with a coating comprising Type A gelatin than when prepared with a coating comprising Type B gelatin. In this regard, it may be observed that the "double patenting" and obviousness issues turn on the same point, i.e., whether it would be obvious to use Type A gelatin to form a soft gelatin capsule containing a free omega-3 polyunsaturated fatty acid composition.

Neither of the earlier patents exemplify a soft gelatin capsule containing a free omega-3 polyunsaturated fatty acid formulation nor provide any suggestion that stability may be improved by using Type A gelatin in place of Type B gelatin. In contrast, both of the earlier patents exemplify a hard gelatin capsule, which, as the skilled person would

appreciate, usually comprises a mixture of Type A and Type B gelatins.

Thus, the skilled person would not have even realized that there was a need to consider improving shelf life and, in any event, would certainly not have expected the significant difference in shelf life that the inventors have observed. There is certainly no suggestion in either of the earlier patents that would have lead the skilled person to consider the process for manufacturing the gelatin could have any impact on the stability of soft gelatin capsules containing a free omega-3 polyunsaturated fatty acid formulation.

As both U.S. Patent 5,792,795 and U.S. Patent No. 5,948,818 fail to suggest a capsule comprising Type A gelatin, Applicants also submit that one skilled in the art would lack the motivation and guidance to modify the claims in a manner that would result in the claimed invention.

Applicants respectfully request that the rejection be withdrawn.

In view of the present amendment and foregoing remarks, therefore, Applicants respectfully submit that the present application is in condition for allowance at the time of the next Official Action.

Respectfully submitted,
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Date: November 25, 2008